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### REMARKS

Claims 21-24 are herewith canceled without prejudice or disclaimer so claims 1-24 stand canceled from the present application matter thereof and claims 25-34 are pending examination on the merits. Claims 31 and 32 are herewith amended and no new claims added.

Applicants respectfully request entry and favorable consideration of the amendments and remark presented herein.

#### **Claim Rejections Under 35 U.S.C. §112**

Claims 25-34 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically the Examiner alleges that the notion of a therapy delivery means operating "independently from said sensor and said signal processor" was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

In addition claims 25-34 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for use of the term "independently." The Examiner asserts that the term is vague since the scope and bounds of "independently" can not be determined.

Applicants respectfully suggest that the Examiner has misinterpreted the claimed invention in that the quoted excerpt alleged to support the rejections (above) merely clarifies that the "trigger signal" causes therapy delivery to occur, independent of any sensor (signal).

therapy delivery means for delivering the therapy upon receipt of a therapy delivery trigger signal, wherein said therapy delivery means operate independently from said sensor and said signal processor.

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An excerpt from the application-as-filed supports the claim limitation (from the paragraph that bridges pages 13-14):

The incorporation of a system clock 122, clock tree 138, and clocked timers 150 and any other clocked logic may be eliminated entirely if the IMD 100 is configured strictly as a monitor mimicking the functions of the aforementioned Medtronic® REVEAL® Insertable Loop Recorder and CHRONICLE® IHM coupled with a capacitive pressure and temperature sensing lead and EGM sense electrodes and data storage is triggered by the patient. Or, the IMD 100 could be configured as a therapy delivery device with therapy initiated by patient action, e.g., by use of the magnet 116 to close reed switch 130, and with or without contemporaneous storage of physiologic data. In this case, the system clock 122, clock tree 138, and clocked timers 150 and any other clocked logic may be eliminated entirely from the IMD 100. FIG. 1 thus depicts a number of components of exemplary IMD system architectures in which the present invention may be implemented to minimize clocked logic, the associated power drain, and the accompanying necessity of an extensive clock tree 138. It will be understood that other circuit blocks may be included in the exemplary IMD system.

Claims 31, 32 and 33 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Specifically claim 31 is asserted to be incomplete for omitting structure cooperative relationship between elements. Applicants herewith amend claim 31 to recite said relationship and thus the ground of rejection has been overcome.

Claim 32 is alleged to be incomplete for omitting an element to sense "cardiac signals." Applicants herewith delete the allegedly incomplete reference to cardiac signals and thus have overcome this aspect of the rejection.

Claim 33 is alleged to lack antecedent basis for "the physiologic signals." However, Applicant reviewed the claim and located adequate antecedent basis is in fact present in the independent claim 25 from which claim 33 depends. That is, claim 25 includes the following (Initial element):

a sensor adapted to couple to human tissue for developing a signal related to a physiologic status of said tissue;

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### **Claim Rejections Under 35 U.S.C. §103**

Claims 25-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over a single reference; namely, U.S. Pat. No. 4,202,341 to Blaser (Blaser).

Applicants respectfully traverse the rejection.

According to the Examiner, Blaser discloses the claimed invention "except for the operating system being at least one integrated circuit" and "except for the sensor being electrodes, an activity sensor, or a blood pressure, temperature, pH, or gas concentration sensor." The Examiner concluded, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system disclosed by Blaser, to include the missing elements.

However, Applicants assert that inspection of Blaser reveals that Blaser is devoid of any mention or use of the terms "sensor," "sense," "sensing," and that Blaser describes only traditional cardiac pacing and sensing via electrodes. Furthermore, Blaser is devoid of any discussion or description of implantable medical devices other than a pacemaker. Thus, the pending claims cannot fairly be deemed obvious over Blaser in that Blaser lacks the very elements claimed.

Nevertheless, according to the Examiner it was known in the art "that pacemakers have circuits and operating systems be at least one integrated circuit to reduce power consumption, size, and capacitance" and "that pacer systems use a sensor being electrodes to provide a bi-polar, localized signal from the particular organ so as not to receive interference from other signals in the body and since it was known in the art that pacer systems use an activity sensor or a blood pressure, temperature, pH, or gas concentration sensor to provide an alternate conventional sensor that senses the heart beating, a sensor that can be located in a different part of the body, and/or a signal to the pacer system allow the system to determine when cardiac therapy is needed.

In general, with respect to 35 U.S.C. § 103, Applicants assert that in connection with combining references to support an assertion of obviousness, it

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is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. **"Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference."** In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). (Emphasis added.)

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to physiologic sensor signals were cited, no official notice was taken, no evidence of any kind was presented other than the conclusory statement that the claimed limitations "are well known in the art." The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. *Id.* Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an evidentiary record. *Id.* at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and

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unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

As previously noted, Blaser discloses merely use of a non-integrated circuit including at least one monostable multivibrator for a pacemaker circuit.

It would appear the rejection is simply an attempt by the Examiner to reject the claimed invention without even offering any specific reference which, if combined, might at least include the recited, individual claim elements. Applicants respectfully suggest that the Examiner has formulated the instant rejection without consideration of the claims as a whole. As reiterated by the CAFC previously, such a practice is not permissible.

In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention.

Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before

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the invention itself, to make the new combination. See In re Rouffet,  
149 F.3d 1350, 1355-56 (Fed. Cir. 1998).

Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004).

Applicants respectfully assert that the Examiner has failed to locate even a series of references (e.g., discrete references such as the "A + B + C" example cited above) and as such the claimed invention should be allowed. For the above and foregoing reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' pending claims under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested. As the present claims are not taught or suggested by the references of record, alone or in combination, Applicant respectfully requests that the Examiner issue a Notice of Allowance in due course for the pending claims.

#### Conclusion

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Date:

18 July 05

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